K080897

510(k) Summary

Date 15 March 2008

Name: Talley Group, Ltd
Premier Way, Abbey Park
Romsey, Hants SO 51 9 DQ England

U.S. Talley Medical
4740 Jadestone Dr.
Williamston, MI 48895
Phone: 517-290-0089 **Fax:** 484-465-5842
Contact: Jack Van Dyke, Director US Operations

JUL 15 2008

Trade Name: Venturi™ Negative Pressure Wound Therapy

Common Name: Powered Suction Pump

Device Classification:	Class II Product Code: JCX Regulation 878.4780 Classification Panel: General and Plastic Surgery
Predicate Devices:	Blue Sky Versatile 1 System KO42134, KO52456 Boehringer Labs Suction Pump system KO61788

Device Description: The Talley Venturi™ system consists of a powered suction pump for the application of vacuum to wounds for fluid removal. Consumables for use with the pump include collection canister, connection tubing, drain, and wound dressing products.

Intended Use: The Talley Venturi™ system is intended for use for patients with acute or chronic wounds that may be benefited by the application of negative pressure therapy and the potential wound healing effects of removal of fluids including wound exudates, irrigation fluids, body fluids, and infectious materials.

Technological Characteristics: The Talley Venturi™ system includes the same type suction pump as the predicate devices, operating at the same pressure ranges. Consumable accessories include collection canister, tubing, drains, and wound dressing components. These accessories correspond with accessories available with the predicate devices.

Specific Performance Testing: **a)** Canister vacuum test is performed on 100% of production units to check for air-tightness and recognition of sensor pins. Loss of vacuum is measured over a prescribed period. Units pass or fail. **b)** Vacuum pump test is performed on 100% of production sub-assemblies measuring flow and pressure. Tested levels are compared with defined minimum values to determine pass or fail. **c)** Soak test is performed on 100% of assembled production pump units and are run for 48 hours prior to final test. **d)** Final system test is performed on 100% of production units. Tests include all functions and buttons, correct pressure calibration, air tightness, canister recognition, warning systems and alarms, charging system operational.

Conclusion: The Talley Venturi™ system is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR -7 2009

Talley Medical
% Mr. Jack Van Dyke
4740 Jadestone Drive
Williamston, Michigan 48895

Re: K080897
Trade/Device Name: Venturi™ Negative Pressure Wound Therapy System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: II
Product Code: OMP
Dated: June 3, 2008
Received: June 10, 2008

Dear Mr. Van Dyke:

This letter corrects our substantially equivalent letter of July 15, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

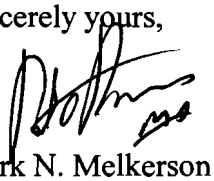
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not

limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K080897

Indications for use

Venturi™ Negative Pressure Wound Therapy system

Indications for Use. Use of the Venturi™ Negative Pressure Wound Therapy system is indicated for use for patients with acute or chronic wounds that may be benefited by the application of negative pressure therapy and the potential wound healing effects of removal of fluids including wound exudates, irrigation fluids, body fluids, and infectious materials. Venturi is intended for use in acute care settings only.

Contraindications. The Venturi™ Negative Pressure Wound Therapy system is contraindicated in the presence of:

Necrotic tissue
Untreated osteomyelitis
Fistula
Wounds with malignant tissue
Exposed vasculature
Exposed nerves
Exposed anastomotic site
Exposed bone or tendons
Wounds with difficult hemostasis

Prescription Use____X____ (21 CFR 801 Subpart D)

OR

Over the Counter Use_____ (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrance of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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